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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------------|------------------------|
| 10/523,444 | 01/31/2005 | Jean Guy G. Gilles | 50304/059001 | 4465 |
| 21559 | 7590 | 05/24/2007 | | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | EXAMINER SZPERKA, MICHAEL EDWARD | |
| | | | ART UNIT 1644 | PAPER NUMBER |
| | | | MAIL DATE 05/24/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|--|--------------------------------------|--------------------------------------|--|
| <p align="center">Office Action Summary</p> | Application No. 10/523,444 | Applicant(s) GILLES ET AL. | |
| | Examiner Michael Szperka | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 17-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1 and 17-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment received January 31, 2005 is acknowledged.
Claims 2-16 have been canceled.
Claim 1 has been amended.
Claims 17-31 have been added.
Claims 1 and 17-31 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 17-22, and 24-27, drawn to anti-idiotypic antibodies, compositions comprising said antibodies, and the cells that produce said antibodies.

Group II, claim 23, drawn to peptides.

Group III, claims 28 and 29, drawn to a method of treating bleeding by administering anti-idiotypic antibodies.

Group IV, claim 30, drawn to a method of making anti-idiotypic antibodies using hybridomas.

Group V, claim 31, drawn to a method of purifying anti-FVIII antibodies.

3. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature of the inventions is the sequences recited in the claims. Mele et al. disclose a peptide which comprises a sequence 100% identical to SEQ ID NO:9 of the instant invention (see attached sequence alignment). As such, the technical feature does not make a

contribution over the prior art of Mele et al. and therefore the instant claims have been found to lack unity of invention.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
May 15, 2007

RESULT 2

AAW00241

ID AAW00241 standard; protein; 108 AA.

XX

AC AAW00241;

XX

DT 25-MAR-2003 (revised)

DT 22-NOV-1996 (first entry)

XX

DE EGF receptor chimeric MAb chMint5 VL chain.

XX

KW Mouse-human chimeric antibody; monoclonal antibody; chMint5;

KW epidermal growth factor receptor; EGF-R; diagnosis; therapy; immunotoxin;

KW immunocytokine; tumour; cancer.

XX

OS Mus musculus.

XX

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|----|-----|---------------------|
| FH | Key | Location/Qualifiers |
|----|-----|---------------------|

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| FT | Region | 24. .34 |
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| FT | | /label= CDR1 |
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| FT | Region | 50. .56 |
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| FT | Region | 89. .97 |
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PN WO9627010-A1.

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PD 06-SEP-1996.

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PF 01-MAR-1996; 96WO-EP000805.

XX

PR 01-MAR-1995; 95IT-FI000036.

XX

PA (ITUY-) ITAL MIN UNIV RICERCA SCI & TECNOLOGICA.

XX

PI Mele A, De Santis R, Ferrer Marsal C, Anastasi AM, Di Massimo AM;

PI Colnaghi MI;

XX

DR WPI; 1996-412776/41.

DR N-PSDB; AAT33446.

XX

PT Murine/human chimeric monoclonal antibody, chMint5 specific for EGF-R -

PT shows a lower immunogenicity when administered to humans.

XX

PS Claim 7; Page 18; 28pp; English.

XX

CC The amino acid sequence (AAW00241) of the light chain variable region

CC (VL) of the epidermal growth factor receptor (EGF-R)-specific mouse-

CC human chimeric antibody chMint5 was deduced from a cDNA clone (AAT33446)

CC obtd. by PCR amplification of murine Mint5 hybridoma DSM ACC2150 cDNA.

CC chMint5 comprises Mint5 VH and VL regions fused to human C-gamma1 and CK

CC regions. Constructs were expressed in CHO cell transfectants. chMint5

CC shows lower immunogenicity than Mint5 when administered to humans. It can

CC be used in diagnostic assays or used to produce immunotoxins or

CC immunocytokines useful for tumour therapy. (Updated on 25-MAR-2003 to

CC correct PR field.)

XX

SQ Sequence 108 AA;

Query Match 100.0%; Score 32; DB 2; Length 108;

Best Local Similarity 100.0%; Pred. No. 16;

Matches 7; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 YVSQSI 7

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Db 50 YVSQSI 56